Remarks

Applicants have amended claim 89. Upon entry of this amendment, claims 37, 89-93 and 107-31 will be pending. The office action is discussed below.

Double patenting

On page 3-4 of the office action, the examiner rejected the claims on double patenting grounds over claims 1-6 of U.S. Patent No. 6,548,068. Applicants note that these type of rejections are intended to prevent an impermissible "prolongation" of the patent term caused by multiple patents possessing claims that are obvious in view of one another. That is, the claimed subject matter must be sufficiently close that issuance of more than one patent would necessarily result in a prolonged term for the same inventive concept. Accordingly, in making an obviousness-type double patenting rejection, the examiner must indicate how the claims of the instant application are sufficiently "obvious" over the other claims so as to result in an impermissible prolongation of patent term. The examiner, however, has not made out a *prima facie* case why the claims are obvious in view of one another, and therefore the rejection should be withdrawn.

The examiner discusses what the "patent '068'" is directed to, but the examiner does not compare the claims in the '068 patent to the rejected claims. Thus, the examiner must show that the subject matter of claim 37, which recites, among other things, a "host cell infected, transfected or induced with a recombinant vector that comprises at least one nucleic acid sequence encoding B7, ICAM-1 and LFA-3" is

rendered obvious by the claims in the '068 patent. The possibility of an overlap in scope between the claims is not the test. Rather, the examiner must show that the claims in the '068 patent render obvious the claims pursued here. The examiner has not done so, and therefore the rejection should be withdrawn.

The invention is not taught by the prior art

On page 4 of the office action, the examiner rejected claim 37 as anticipated by Hargreaves. Applicants respectfully traverse this rejection.

As explained previously, in order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim term is contained in a single prior art reference. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); *see also* MPEP § 2131 (August 2001). Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. *See* MPEP §§ 707.07(g); 2111.01 (August 2001). Claims are to be given their broadest reasonable interpretation consistent with applicants' specification. *See In re Zletz*, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms reasonably allow); MPEP § 2111 (August 2001).

Not only must the claim terms, as reasonably interpreted, be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said to have been already

within the public's possession, which is required for anticipation. *See Akzo, N.V. v. U.S.I.T.C.*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); *In re Brown*, 141 USPQ 245, 249 (CCPA 1964).

Hargraeves at page 1512 discusses that DAP.3/DR1 cells that express a mouse B7 gene. These cells were transfected with cDNAs clones for LFA-3 and/or ICAM-1. Accordingly, these cells were not recombinant vector, such as a recombinant poxvirus, that comprises at least one nucleic acid sequence encoding B7, ICAM-1 and LFA-3. That is, the cells of Hargreaves were not transfected with a vector that encodes these three types of co-stimulatory molecules. Accordingly, Hargreaves cannot anticipate the office action.

The claims stand enabled

On pages 2-3 of the office action, the examiner rejected the claims on enablement grounds. Specifically, the examiner contends that is would take undue experimentation to show that the host cell comprising a vector could be used to "prevent any or all disease." Applicant traverse this rejection.

In the world of vaccination, preventative vaccines are used against infectious diseases prior to infection, whereas treatment vaccines are directed against cancer in patients where it has already occurred. Both types of vaccines, however, share the common property of being used to stimulate the immune system against the given target, such as a pathogen or a cancer cell.

The claimed invention presents a new approach towards the stimulation of the immune system. That is, the claimed invention permits an enhancement of the immune system through the *in vitro* activation of T-lymphocytes. This activation can be performed by exposing T lymphocytes to a host cell that has been infected, transfected or induced with a recombinant vector that comprises at least one nucleic acid sequence encoding B7, ICAM-1 and LFA-3, wherein the vector permits expression of nucleic acid sequences in the host cell and then administering the activated T lymphocyte to an individual in an amount sufficient to enhance an immune response. These vectors include recombinant poxviruses that contain sequences encoding B7, ICAM-1 and LFA-3.

As explained previously, the ability of such vectors has been demonstrated in the specification, as shown by the wealth of data in applicants' specification showing the effectiveness of the claimed invention. Examples 24-27 discuss the co-stimulation and T-cell proliferation effects of embodiments of the claimed invention. Example 28 demonstrates desirable effects on apoptosis. Example 29 discusses anti-tumor effects of embodiments of the invention. Examples 30-33 also contain positive data on co-stimulation using embodiments of the invention.

The claimed invention is described in the specification

On pages 5-6 of the office action, the examiner made a new rejection based upon written description. The examiner rejected claims 107-20 and 122-25 due to the antigens listed in the claims. Applicants respectfully traverse this rejection.

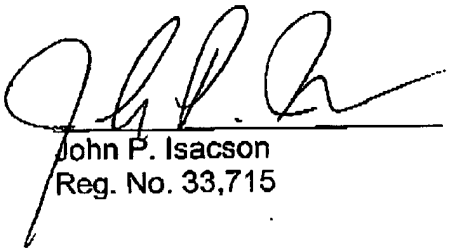
The USPTO issued its final guidelines for written description (66 Fed. Reg. 1099) in early 2001, republished at MPEP § 2163. The written description guidelines first instruct examiners to determine what the claim as a whole covers and then review the entire specification to determine whether all subject matter that is essential to the invention is actually recited in the claims. See written description guidelines at II(A)(1), (2). Next, the examiners are instructed to determine whether the applicant was in possession of all that is claimed. See the written description guidelines at II(A)(3). According to the guidelines, possession of a claimed invention can be shown by disclosure of structural characteristics, functional characteristics that correlate with structure or combinations thereof. See the written description guidelines at II(A)(3)(a). Claims that encompass a genus must be supported by a written description of a representative number of species. See the written description guidelines at II(A)(3)(a)(2). The written description of the representative species of the genus can be shown by disclosure of structural characteristics, functional characteristics that correlate with structure or combinations thereof. Applicants submit that the examiner has not satisfied these guidelines in making the rejection, which alone is grounds for withdrawal of the rejection. Nevertheless, applicants demonstrate below that the structural requirements set forth in claims 107-20 and 122-25 find correspondence in the specification at pages 33-37 and original claims 19-31. Note that the original claims are part of the specification under the first paragraph of 35 USC § 112. See MPEP § 2163.06(III) (Rev. 1, Feb 2003).

The antigens recited in the claims are disclosed in the specification, along with sources for the antigen sequences. Thus, applicants possessed the inclusion of these antigens in the recombinant vectors, and therefore the claimed invention is at least 'sufficiently derivable' from the specification. *See Union Oil Co. of Calif. v. Atlantic Richfield Co.*, 208 F.3d 989, 1000-01 (Fed. Cir. 2000). The above discussion shows that it is clear that applicants had possession of the subject matter claimed in claims 107-20 and 122-25. Given the correspondence and applicants' identification of this correspondence herein, a heavy burden is placed upon the examiner to reject the claims given that the specification is presumed in compliance with 35 USC § 112. *See* MPEP § 2163.04 (Rev. 1, February 2003).

Request

Applicants submit that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,



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